

REMARKS

Applicant intends this response to be a complete response to the Examiner's 31 November 2005 Final Office Action. Applicant has labeled the paragraphs in his response to correspond to the paragraph labeling in the Office Action for the convenience of the Examiner.

DETAILED ACTION

1. The amendment filed August 28, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-43 are pending.
3. In the reply filed on May 18, 2005, applicant elected of Group II, claims 8-13 and 29-42 (now including claim 43), *Allium cepa* for species A and rhinovirus for species B without traverse.
4. Claims 1-7, 11, 14-38, 41, and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on May 18, 2005.
5. Claims 8-10, 12, 13, 39-40 and 43 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 112

6. Claims 8-10, 12, 13, 39-40 and 43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Examiner contends as follows:

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claim 8 to state that the viral infection is treated with a composition comprising greater than 95% of the particulate material from *Allium cepa*. However, applicant's specification does not support the use of a composition comprising the specific percentage of *Allium cepa*. The specification discusses a percentage of greater than 95% in regards to the particle sizes being between 1 to 1,4000 microns. Specifically, the specification states "Preferably, the utilize procedure for particulating the processed dehydrated *Allium*, preferably *Allium cepa*, material will result in most (greater than 95%) of the particles or granules in the resultant composition having an average size ranging from 1 to 1,400 microns...(see page 11, lines 5-8)." The specification does not support including the *A. cepa* in the pharmaceutical composition at amounts greater than 95% only that the particle distribution is at least 95% between 1 to 1,400 microns. Thus, the addition of the limitation requiring 95% of *A. cepa* in the pharmaceutical composition does not have support in the specification as originally filed. The specification does discuss specific dosage of *A. cepa* to administer, but does not state the percentage of *A. cepa* in these dosages.

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Applicants understand the Examiner's understanding of the 95% and agree with the Examiner's reading and have amended the claims to remove this reference.

Claim Rejections - 35 USC § 103

7. **Claims 8-10 and 12** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) for the reasons set forth in the previous Office action.

The Examiner contends as follows:

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach using onion in the amounts claimed by applicant. However, the reference teaches only specifically mentions onion as one active ingredient in the method to treat the common cold. The reference does not specifically teach the percentage of onion included in the compositions. However, the dosage of a specific ingredient is well known in the art to be a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount dosage of onion to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

Applicants disagree with the Examiner's reliance on Chinese Pat. Appl. No. 1089152 A (1994). The Derwent abstract is not complete and not in agreement with the abstract published by the EPO on espacenet (copy of espacenet display attached). The abstract for Chinese Pat. Appl. No. 1089152 A (1994) on espacenet reads as follows:

Onion product series in the form of tablet, instant granules, capsule, powder, emulsion, etc. includes food, beverage, health-care medicine and new drug, which are made up by adding Chinese herbal medicines, vegetables and food in pure onion product obtained by means of squeeze, organic solvent extraction and distillation. It may be used to cure hyperlipemia, hypercholesterol, arteriosclerosis, hypertension, arthritis, common cold, dysentery, rabies, diabetes, and baldness.

Applicants assert that this invention is non-obvious over the cited prior art because the prior art does not disclose, teach or even suggest "a particulate, dehydrated plant material" as required in the claims of this application over Chinese Pat. Appl. No. 1089152 A (1994).

During the last stage of examination, Applicants pointed out a discrepancy between the

Examiner's Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) and the EPO English abstract of Chinese Pat. Appl. No. 1089152 A (1994). The EPO abstract disclosed that the Chinese Pat. Appl. No. 1089152 A (1994) composition was formed from a liquid derived from onion by extraction and distillation. The Examiner then requested a full translation of Chinese Pat. Appl. No. 1089152 A (1994), which was forwarded to Applicant. The full translation is in agreement with the EPO abstract and not the Derwent English abstract. The Chinese Pat. Appl. No. 1089152 A (1994) makes it clear that their composition contains an onion juice prepared "from onion by means of pressing, concentrated, dried, ground, and developed into the powder preparation . . ." Chinese Pat. Appl. No. 1089152 A (1994) at claim 2. Thus, Chinese Pat. Appl. No. 1089152 A (1994) does not disclose, teach or even suggest a particulate, dehydrated patent material, but discloses a herbal medicament prepared using a juice derived "from onion by means of pressing, concentrated, dried, ground, and developed into the powder preparation . . ." Chinese Pat. Appl. No. 1089152 A (1994) at claim 2. The Chinese Pat. Appl. No. 1089152 A (1994) composition clearly is not a particulate, dehydrated plant material; it is a juice of a plant material that is highly processed and later dewatered to form a powdered material.

Because Chinese Pat. Appl. No. 1089152 A (1994) does not disclose, teach or even suggest a method of administering a particulate, dehydrated plant material composition, but only a method of administering an extracted and distilled composition irrespective of its final form, Chinese Pat. Appl. No. 1089152 A (1994) does render the pending claims of this invention obvious. Applicants, therefore, respectfully request a reversal of the Examiner's 103(a) rejection.

8. **Claims 8-10, 12, 13, 39-40 and 43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent English abstract of Chinese Pat. Appl. No. 1089152 A (1994) in view of US Pat. No. 4,409,237 for the reasons set forth in the previous Office action.**

The Examiner contends as follows:

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that CN '152 teaches away from using a high dosage of onion in the composition based on the "significant amount" of other material included in the composition of CN '152. However, CN '152 is not considered by the examiner to require a "significant amount" of material other than the onion. The reference teaches only one active ingredient, onion, and states that this can be administered in various pharmaceutical forms. No other ingredients are specifically required. Thus, CN '152 is not considered to teach away from using a high dosage of onion. Therefore, the claims are considered properly rejected for the reasons of record.

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Applicants repeat their arguments relating to Chinese Pat. Appl. No. 1089152 A (1994) as set forth above. While US Pat. No. 4,409,237 discloses powders and humidity and Chinese Pat. Appl. No. 1089152 A (1994) discloses compositions that can be in the form of a powder, Chinese Pat. Appl. No. 1089152 A (1994) is not a method of administering a composition comprising a particulate, dehydrated plant material as is true in the present claims. As stated above, the Chinese Pat. Appl. No. 1089152 A (1994) composition contains a juice prepared "from onion by means of pressing, concentrated, dried, ground, and developed into the powder preparation . . ." Chinese Pat. Appl. No. 1089152 A (1994) at claim 2.

The combination of Chinese Pat. Appl. No. 1089152 A (1994) and US Pat. No. 4,409,237 does nothing to remove the deficiencies of Chinese Pat. Appl. No. 1089152 A (1994) as it relates to the nature of the composition being administered – a composition comprising a particulate, dehydrated plant material – not a composition derived from squeezing, solvent extracting and distilling.

Because the combination of Chinese Pat. Appl. No. 1089152 A (1994) and US Pat. No. 4,409,237 does not disclose, teach or even suggest a method of administering a particulate, dehydrated plant material composition, but only a method of administering a powdered composition containing a juice prepared "from onion by means of pressing, concentrated, dried, ground, and developed into the powder preparation . . ." (Chinese Pat. Appl. No. 1089152 A (1994) at claim 2), the combination does render the pending claims of this invention obvious. Applicants, therefore, respectfully request reversal of the Examiner's 103(a) rejection.

Having fully responded to the Examiner's Final Office Action, Applicants respectfully strongly urge that this application be passed onto allowance.

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If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicant's attorney Robert W. Strozier at 713.977.7000.

The Commissioner is authorized to debit any underpayment or credit any overpayment to Deposit Account 501518.

Respectfully submitted,



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Date: January 27, 2009